I hereby certify that this correspondence is being transmitted via facsimile to the Commissioner for Patents, c/o C. Wilder at (703) 308-4242 on the date shown below.

Signature: _____
(Jeffrey S. Sharp)

Dated

Docket No.: 28911/36128/US
(PATENT)

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Patent Application of:
Alison Hopkins

Application No.: 09/485,245

Group Art Unit: 1655

Filed: March 27, 2000

Examiner: C. Wilder

For: LABELLING COMPOSITION AND METHOD

DECLARATION OF ALISON HOPKINS UNDER 37 CFR 1.132

Box AF
Commissioner for Patents
Washington, DC 20231

1. I, Alison Hopkins, declare that I am the inventor of the subject matter described and claimed in the above-identified patent application and that I am experienced in the arts of molecular biology and including the art of random prime labeling of nucleic acids.

2. I submit this declaration to address issues raised in the Office Action dated May 1, 2002 in the above-identified application as well as in the Interview with the Examiner conducted May 14, 2002.

3. In response to the questions presented about the identity and criticality of the buffer used in the experiments presented in the specification, I declare that the buffer recited in claim 2 is not critical to the demonstration of the unexpected results presented on pages 8 and 9 of the application. The specification at page 7, lines 2 and 3 describes a commercially available nucleotide buffer (N5000/N5500 Amersham International plc, see the Exhibit attached hereto) which comprises Tris-HCl, ph 7.8, $MgCl_2$ and 2-mercaptoethanol. The specification further teaches that other buffers could be used depending upon the particular polymerase enzymes at page 4, lines 13 through 17 of the specification. The selection of this suitable buffer would be within the scope of a knowledgeable person and would not influence implementation of the invention.

Application No.: 09/485245

4. I declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the above-identified application or any patent issuing thereon.

Alison Hopkins

Alison Hopkins

October 22nd, 2002

Nick translation kit

N 5000 For radioactive probe preparation
N 5500 For radioactive and non-radioactive probe preparation

STORAGE
Store at -15°C to -30°C
in a non frost-free freezer.

STABILITY
Stable for 3 months,
stored as recommended

Warning: For research use only.
Not recommended or intended for diagnosis of disease in humans or animals. Do not use internally or externally in humans or animals.

amersham pharmacia biotech

COMPONENTS OF THE SYSTEM

Nick translation systems	N 5000	N 5500
Nucleotide/buffer solution; 100mM each of dATP, dGTP and dTTP in Tris HCl pH7.8, 2 mercaptoethanol, and $MgCl_2$	400µl	-
Nucleotide solutions; in Tris-HCl pH7.8, 2-mercaptoethanol and $MgCl_2$		
300µM dATP	-	150µl
300µM dCTP	-	150µl
300µM dGTP	-	150µl
300µM dTTP	-	150µl
Enzyme solution; 0.5 units/µl DNA polymerase I and 10pg/µl DNase I in Tris-HCl pH7.5, $MgCl_2$, glycerol and bovine serum albumin	200µl	200µl
Standard DNA solution; 200ng/µl *Hind* III digested lambda DNA in 10mM Tris-HCl pH8.0, 1mM EDTA	25µl	25µl
Water	2x1ml	2x1ml

Contents	Page
Components of the system	2
Safety warnings and precautions	4
Description	5
Critical parameters	8
Additional solutions and reagents required	9
Nick translation system protocols	10
Storage and stability	10
Large scale preparation of radioactively labelled probe	11
Preparation of non-radioactively labelled probes using (N 5500)	16
Additional Information	19
Monitoring information	19
Radiolabelled nucleotides	19
Non-radioactively labelled nucleotides	20
Size analysis of probes for *in situ* hybridization	24
Removal of unincorporated nucleotides	24
Spin columns	25
Selective precipitation of labelled DNA	25
Quality control	25
Related products	26
Background references	27